Decision Memo for Lymphedema Pumps (CAG-00016N)

Decision Summary

Revise Coverage Issues Manual 60-16 so that:

1. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition which may be due to such causes as Milroy's Disease or congenital anomalies. Secondary lymphedema, which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as by surgical removal of lymph nodes, post radiation fibrosis or scarring, among other causes. The keystones of lymphedema treatment are elevation, compression and exercise.

2. A pneumatic compression device will not be covered as initial therapy for lymphedema in the home setting. A patient must first undergo a four-week trial of conservative therapy, which includes the use of an appropriate compression garment, exercise and elevation. This garment does not need to be custom-fabricated; however, it does need to be a graduated compression stocking/sleeve. A pneumatic compression device is covered if a physician determines after such a trial that there has been no significant improvement, or if significant symptoms remain.

3. Encourage patients to use compression garments between pump sessions to prevent reaccumulation of fluid.

All other sections of this policy remain unchanged.

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Decision Memo

TO: File: CAG-00016N
Pneumatic Compression Devices (Used for Lymphedema)

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RE: National Coverage Decision
DATE: May 3, 2001

The memorandum serves four purposes: (1) outlines the description and treatment of lymphedema (2) reviews the history of Medicare coverage for pneumatic compression pumps in the treatment of patients with primary and/or secondary lymphedema; (3) presents and analyzes the relevant clinical and scientific data related to the use of pneumatic compression pumps, and (4) delineates the reasons for revising the national coverage policy to distinguish between primary and secondary lymphedema, as well as remove the current coverage language referring to this therapy as a "treatment of last resort".

Pneumatic compression devices are also used to treat venous insufficiency. Use of pneumatic compression devices for this indication has been referred for a technology assessment, and will be the subject of a separate decision memorandum. This decision memorandum does not address, nor does it make any changes in the policy regarding coverage of pneumatic compression pumps for the treatment of venous insufficiency, including treatment of venous stasis ulcers. It also does not address edema of the upper/lower extremity that is not truly lymphedema. In addition, it does not make any changes in the present policy regarding the use of segmented versus nonsegmented pumps.

Clinical Background

The main function of the lymphatic system is to clear fluid from the interstitial tissues of the body and return it to the bloodstream via a system of lymphatic vessels and lymph nodes. Lymph fluids consist of water, proteins, and other solutes that are found among interstitial tissues. Lymphedema is an abnormal collection of excessive tissue proteins, edema, chronic inflammation, and fibrosis that results in accumulation of this fluid in the interstitial spaces, principally subcutaneous fat, as a result of inadequate clearance by the lymphatic system.

Lymphedema can be divided into (1) primary and (2) secondary forms. Primary lymphedema is a relatively uncommon condition that is usually congenital in nature, at times representing an inherent deficiency of the lymphatic system (e.g. Milroy's Disease). Secondary lymphedema, which is more common, is an acquired defect of the lymphatic system. Lymph transport is interrupted due to physical disruption or compression of lymphatic channels. The most common etiologies of secondary lymphedema include surgical procedures involving removal of the lymph nodes, obstruction of the lymphatic system by malignant tumors, local radiation treatment, and some traumatic injuries. In the United States breast cancer surgery is the most common cause of secondary lymphedema. The incidence of lymphedema among women who develop breast cancer is about 15-20%. At one-year post surgery, Markowski and colleagues observed that lymphedema was minimal in 22.4% of patients, moderate in 5.2%, severe in 3.4%.[1]

No cure for lymphedema presently exists. The conservative management of lymphedema is guided by a basic principle: increased pressure on an edematous extremity to enhance lymph drainage. Conservative management typically includes positioning (elevation), massage, exercise, and compression garments or wraps.

Medications have also been tried. Although diuretics have not been proven to be effective, there has been limited treatment success with benzopyrones. This class of drugs presumably work by stimulating macrophage activity with resultant proteolysis; this proteolysis then decreases oncotic pressure and subsequently the edema. Benzopyrones can cause liver damage, so general usage is limited.

Diagnosis of lymphedema is based on clinical criteria. The patient's subjective awareness of symptoms, such as swelling, fullness, tightness or heaviness of a limb, may herald the presence of pathology, and may precede the ability of the clinician to detect physical changes in the limb. The physician finding of a difference in the measurement of limb circumference is sometimes considered evidence of presence of lymphedema. In addition, radioisotope indirect lymphoscintigraphy is sometimes used for the detection and quantification of lymphatic dysfunction.

Although lymphedema is not life-threatening, it can impact significantly on the quality of life of beneficiaries. It can be uncomfortable/painful as well as disfiguring and disabling. At times, it can lead to cellulitis or lymphangitis.

FDA Review

These devices are cleared for marketing under 510 (k) process. No clinical data was necessary for clearance since they existed prior to passage of the Medical Device Amendments of 1976.

History of Medicare Coverage of Pneumatic Compression Pumps

Medicare has covered pneumatic compression pumps for the treatment of lymphedema since 1986. The policy simply stated "that segmental and non-segemental type pumps are appropriate for use in the home for the treatment of intractable lymphedema of the extremities." Pneumatic compression pumps generally are either segmented or non-segmented pumps. These pumps are reimbursed under 3 codes: (1) E0650-non-segmented home model; (2) E0651-segmented home model without calibrated gradient pressure; and (3) E0652-segmented home model with calibrated gradient pressure.

In February 1993, the Office of Health Technology Assessment (OHTA) of the Department of Health and Human Services issued a technology assessment, which stated that "all pneumatic compression devices (single or multiple chambered with or without calibrated pressure gradients) are similarly effective in the treatment of lymphedema."[2] They also stated that the multi-chambered devices may be more effective than a single-chambered device in selected patients, although such patients could not be reliably defined.

In June 1995, HCFA issued a new policy on Pneumatic Compression Pumps.[3] The new policy stated that a segmented device with manual control (HCPCS code E0652) is covered only when there are unique characteristics that prevent the individual from receiving satisfactory pneumatic treatment using a less costly device, e.g. significant skin scars or the presence of contracture or pain caused by a clinical condition that requires the more costly manual control device.

Coverage Issues Manual §60-16:

"…Pneumatic compression devices are only covered as a treatment of last resort, i.e., other less intensive treatments must have been tried first and found inadequate. Such treatments would include leg or arm elevation and custom fabricated gradient pressure stockings or sleeves. Pneumatic compression devices may be covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include (1) the patient's diagnosis and prognosis; (2) symptoms and objective findings, including measurements which establish the severity of the condition; (3) the reason the device is required, including the treatments which have been tried and failed; and (4) the clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home….

In 1998, the Blue Cross Blue Shield Technology Evaluation center (TEC) prepared an assessment comparing the efficacy of different types of pneumatic compression pumps. This report did not deal with the criteria for determining the necessity for pump use, but rather with the relative merits of one type of pump over another. The technology assessment concluded that there is "insufficient evidence to permit conclusions regarding whether the efficacy of lymphedema pumps varies across pump type. Substantially more evidence involving direct comparisons of pump types would be required in order to make this determination with any certainty."[4] This report supported the June, 1995 HCFA policy.

Timeline of Recent Activities

HCFA had been asked several times by manufacturers over the past few months to review certain aspects of our current national coverage policy. In particular we have been asked to remove the "treatment of last resort" language. As mentioned earlier, there are different etiologies of lymphedema, and all may not be treated the same way. The use of pneumatic compression pumps for the treatment of venous insufficiency is being referred for a technology assessment and will be the subject of a separate decision memorandum. We have received a request to consider coverage for Complex Decongestive Therapy (CDP), a protocol for lymphedema treatment which includes therapeutic massage. That request is currently under review and is not part of this decision memorandum.

This decision memorandum also does not make any changes in the policy regarding coverage criteria for nonsegmented versus segmented compression devices. The present policy remains in place.

Summary of Evidence

A total of 17 articles were reviewed as part of this decision:

- 2 Clinical Trials
- 6 Case series
- 3 Review Articles
- 1 Position Statement
- 1 Case study
- 4 Opinions/Editorial

Specific information on each article/study can be found in **Appendix A: Literature Review**.

The two clinical trials were Kim-Sing (1987) and Klein (1988). Both dealt with the efficacy of the Wright Linear Pump; these studies were part of a Phase II trial to determine the efficacy of the pump.[5]

Kim-Sing enrolled fifteen patients with postmastectomy lymphedema of the arm. Ages ranged from 35 years to 81 years. Patients underwent a total of 38 hours of pumping, using a sequential intermittent compression pump, over a 48 hour period. Of 15 patients, 12 had previously used a different brand of pump for more than 3 months but had discontinued its use due to poor results. At the end of the protocol, 8 of the 15 patients had a reduction in limb circumference of at least 2 cm, representing an average 49% reduction in edema. Authors point out that conservative management includes elevation, isometric exercises, and elastic sleeves. No long-term followup information was provided.

Klein (1988) enrolled 73 patients with lower-extremity edema from various causes (41% idiopathic, 34% post-surgery, 11% congenital, 14% other). Authors used a 48-hour treatment protocol with pumping periods ranging from 2- 8 hours followed by one-hour rest intervals. At the end of the 48 hour study, over 65% of patients showed a decrease in limb circumference post-therapy.

Pappas (1992) studied 49 patients with lymphedema, 6 upper extremity and 43 lower extremity. Protocol was a 48-72 hour treatment period, with 6-8 hour pumping sessions followed by rest periods. Patients were grouped into full responder, partial responders, and non-responders. There were statistically significant results between pre- and post-treatment, although there was no report on the overall percent reduction for the entire group of patients. The study also assessed the long-term effects of a program entailing 1) sequential pumping, 2) elastic compression stockings to maintain the post pump results and 3) daily skin care. The author described conservative treatment as including positioning, massage, exercise, compression garments and pumps. In the long-term follow-up 26 patients maintained full response while 10 patients maintained a partial response.

Boris (1998) was a retrospective study to determine the risk of genital edema after external pumping for lower limb lymphedema. The study setting was a single treatment facility and involved 128 patients with lower limb lymphedema. Patients were separated into 2 groups 53 patients used a pump and 75 did not use a pump. Of the 53 patients who used the pump, 23 developed genital edema, while only two of the 75 patients who did not use the pump developed this condition. Data was statistically significant. The incidence of genital edema appeared to be unaffected by age, sex, grade, or duration of lymphedema.

Position Statements

Although there are no formal position statements from clinical specialty societies on the use of lymphedema pumps, there is a statement from the American Cancer Society dealing with lymphedema s a result of breast cancer. In 1998, the American Cancer society organized a group of 60 participants into five workshops and charged each with a dimension of the current challenge of lymphedema.[6] As part of Workgroup III: Diagnosis and Management, the workgroup concluded that:

"..while there are different therapeutic approaches to lymphedema, consensus has not been reached on whether one approach is preferable to another, or under what circumstances one approach may be more appropriate than another…. future research should attempt to determine the relative efficacy of each of the components of the compression treatment program; determine the optimal timing for the institution of various existing treatment modalities within the natural history of the disease and investigate the role of early detection and aggressive therapy in reducing the severity of lymphedema and its likelihood of progression."[7]

HCFA Analysis

In addressing a revision of the national coverage policy on the use of compression pumps for the treatment of lymphedema, the following questions arise:

- What constitutes an initial regimen of conservative care?
- Is there adequate evidence to determine that the use of compression pumps as a first-line therapy is equivalent to conservative care?
- Are there patients who may not benefit, or be harmed by the use of the pump?

It is noteworthy that despite several decades of use, only two clinical trials, involving less than 100 patients, have been conducted to evaluate compression pumps. Neither of these trials compared use of the pumps to conservative therapy. Given the prevalence of this condition, and the morbidity associated with it, HCFA would have expected to find more and better clinical data on this treatment, especially since these pumps have been covered since 1986.

Although no cure exists for lymphedema and the treatment regimen does have some variation, there is general consensus in the literature that a conservative regimen consists of a minimum of elevation, exercise, and massage. Compression garments are also listed as part of conservative care.[8] At the same time, it can be acknowledged that these conservative treatments will not be effective in all situations, and in some circumstances may be impractical. However, conservative treatment should at least be given an adequate attempt, since it is non-invasive and largely without risk.

The currently available literature does not support the use of compression pumps as first-line therapy. As seen in the following table, the majority of studies reviewed demonstrate that patients typically tried conservative therapy prior to pump usage. This trial of conservative therapy typically was at least four weeks duration.

Name of Author	*Conservative therapy prior to pump use*	*Recommends Use of Compression Garments after pump use*
Benison (1986)	X	X
Boris (1998)	X	X
Dennis (1993)		X
Hopkins (1996)		X
Kim-Sing (1987)	X	
Klein (1988)	X	X
Pappas (1992)	X	X
Richmond (1985)	X	X
Swedborg (1984)	X	X

In addition, most of the articles explicitly stated that compression pumps are not considered part of a conservative care regimen. Brennan, Kim-Sing ,Vasudevan all examined the issue of conservative care for the treatment of lymphedema. All agreed that proper conservative care consists of positioning, exercise and the use of compression garments. In addition, most authors emphasized that compression garments must be worn immediately and consistently after pumping in order to maintain reduction in edema.

Pneumatic compression pumps are not completely without risk, and therefore should not be considered equivalent to conservative therapies. A few articles concluded that pumps may actually increase morbidity in some patient populations. For example, Casley-Smith noted "...superficial lymphatic vessels are very small and fragile and pumps can easily damage them." Also, "…deeper vessels may be encouraged to drain by the pumping, if their drainage is inadequate or is blocked further along the lymphatic drainage system a new area of lymphedema is formed. This can lead to the formation of fibrous tissue like cuff around the upper part of the limb. This then contracts and strangles remaining lymphatics."[9] Other adverse affects in pneumatic compression may be pain, numbness, peripheral nerve damage, infection and increased skin fibrosis.[10] Of note, few studies examined home use of these devices but instead focused on inpatient setting with physician supervision.

In addition, the use of these pumps is not appropriate for all patients with lymphedema. Several articles mentioned absolute and relative contraindications to use of a pump. Boris (1998) indicated that compression pump therapy for the lower limb might produce genital edema, although it should be noted that such findings have been infrequently reported. Brennan (1998) identified possible contraindications to pump use, which include pre-existing infection, metastatic disease and ongoing radiation.

Conclusion

Data are quite limited on the effectiveness of a pneumatic compression pump for the treatment of lymphedema.[11] Available evidence is suggestive that these pumps may benefit a subset of patients with lymphedema. The specific indications and treatment regimens which would be most effective, however, remain to be defined. A pump may be an appropriate therapy for certain patients that have not been able to reduce limb swelling by conservative treatment. Such conservative treatment must include the use of a compression garment.

Whereas the scientific evidence for the use of pumps is suggestive, it is not conclusive. In addition, studies typically enrolled patients that previously had undergone a trial of conservative therapy. Moreover, the study time was typically limited to a few days. Given that there is no clear demonstration of the effectiveness of these pumps as a first-line therapy, conservative therapy should always be tried first. This trial should be of at least four weeks duration, since that time period was typically the minimum trial period in the studies reviewed. Conservative options involve minimal risk and are less intrusive on a patient's quality of life.

It is also important to note that there are few published studies regarding the use of these devices in the home setting. The importance of physician oversight and evaluation when a patient is using a pump in the home setting is supported by the potential for development of complications in the absence of such monitoring.

As stated earlier, there are few well-designed studies concerning the use of these pumps for the treatment of lymphedema. We strongly encourage studies of this therapy, with attention to standardization of protocols for treatment, evaluation of the benefit and risks of pump use particularly as compared to the benefits and risks of conservative treatments and other therapies, such as complex decongestive physiotherapy. We are interested in revisiting this issue in 1-2 years to review new data, and make any necessary revisions to this coverage policy.

DECISION:

Revise Coverage Issues Manual 60-16 so that:

1. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition which may be due to such causes as Milroy's Disease or congenital anomalies. Secondary lymphedema, which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as by surgical removal of lymph nodes, post radiation fibrosis or scarring, among other causes. The keystones of lymphedema treatment are elevation, compression and exercise.

2. A pneumatic compression device will not be covered as initial therapy for lymphedema in the home setting. A patient must first undergo a four-week trial of conservative therapy, which includes the use of an appropriate compression garment, exercise and elevation. This garment does not need to be custom-fabricated; however, it does need to be a graduated compression stocking/sleeve. A pneumatic compression device is covered if a physician determines after such a trial that there has been no significant improvement, or if significant symptoms remain.

3. Encourage patients to use compression garments between pump sessions to prevent reaccumulation of fluid.

All other sections of this policy remain unchanged.

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1 Brennan MJ. Lymphedema Following the Surgical Treatment of Breast Cancer:A Review of Pathophysiology and Treatment, Journal of Pain and Symptom Management 1992;7:110-116.

2 Office of Health Technology Assessment. Lymphedema pumps: pneumatic compression devices, 1993.

3 Coverage Issues Manual §60-16

4 Lefevre, F. Special Report: Comparative efficacy of different types of pneumatic compression pumps for the treatment of lymphedema, Blue Cross Blue Shield Association, 1998.

5 Note that there are various types/manufacturers of the pumps.

6 American Cancer Society Workshop on Breast Cancer Treatment-Related Lymphedema: Recommendations and Research Initiatives. Cancer Journal for Clinicians 2000:50:303-305.

7 American Cancer Society Lymphedema Workshop, Workgroup III, Diagnosis and Management of Lymphedema

8 Compression garments are typically a graduated stocking/sleeves. Simple bandages and wraps would not be considered an adequate compression garment.

9 Casley-Smith JR, Other Treatments for Lympheodema, 1994 (unpublished)

10 Szuba A, Pneumatic Compression Pumps in Treatment of Lymphedema, A Fried or Foe, 2000 (Presentation)

11 Again, this decision relates only to primary and secondary lymphedema; it does not address the use of these pumps for venous insufficiency.

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